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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,409	08/21/2003	Wouter Matthijs Muijs Van de Moer	K1008/20453	7769
3000	7590	01/20/2006	EXAMINER	
CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 01/20/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,409

Applicant(s)

VAN DE MOER ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/28/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/369264.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 7, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Richards et al. (4,669,473). Richards et al. disclose, at least in figures 2 and 8 and in col. 3, lines 37-46 and col. 6, lines 6-19, an assembly usable for introduction into an incision and for sealing an opening in the wall of a blood vessel having a vessel wall with inner and outer surfaces, where the assembly includes, inter alia, a sheath (105) or first member, an occlusion element (15b) constructed and arranged to be inserted into an incision and directed to seal an opening in the wall of the blood vessel; a resorbable retaining thread (10b) with a distal section and a proximal section and arranged to receive a force for causing engagement of the occlusion element with the inner wall surface of the vessel, and a locking element (13) arranged to be slidably mounted on the retaining thread and apply force to the outer wall surface of the blood vessel. Note: The introductory statement of intended use (e.g., “for introduction into an incision and for sealing an opening in the wall of a blood vessel having a vessel wall with inner and outer surfaces”) has been carefully considered but deemed not to impose any structural

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limitations on the claims patentably distinguishable over the device of Richards et al., which is capable of being used as claimed if one desires to do so.

3. Claims 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kensey (4,890,612). Kensey discloses, at least in the figures and in col. 4, lines 25-51, a bioabsorbable occlusion assembly or sealing device for introduction into an incision and for sealing an opening in the wall of a blood vessel having a vessel wall with inner and outer surfaces, where the assembly includes, inter alia, a spreadable occlusion element (106) constructed and arranged to be inserted into an incision and directed to seal an opening in the wall of the blood vessel; a retaining thread (104) with a distal section and a proximal section and arranged to receive a force for causing engagement of the occlusion element with the inner wall surface of the vessel, and a locking element (106) arranged to be slidably mounted on the retaining thread, maintain tension upon the retaining thread, and seal a puncture in the blood vessel

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3-6 and 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Richards et al. Richards et al. disclose the invention substantially as claimed. Richards et al. disclose an assembly usable for introduction into an incision and for sealing an opening in the wall of a blood vessel having a vessel wall with inner and outer surfaces, where the assembly includes, inter alia, a sheath (105), a second resorbable segment (15b) constructed and arranged to be inserted into an incision and directed to seal an opening in the wall of the blood vessel; a first resorbable segment (10b) with a distal section and a proximal section and arranged to receive a force for causing engagement of the occlusion element with the inner wall surface of the vessel, and a third segment (13) or locking element arranged to be slidably mounted on the retaining thread and apply force to the outer wall surface of the blood vessel. However, Richards et al. do not specifically disclose that the third segment or the locking element is resorbable. Nevertheless, Richards et al. teach, in col. 3, lines 37-61, that surgical fasteners can be made resorbable or non-resorbable. Thus, it would have been a matter of obvious design choice to form the third segment or locking element out of a resorbable material. The choice would be dependent upon the therapeutic demands for a resorbable fastener and whether it is to be implanted within a patient's body.

6. Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (4,890,612) in view of Richards et al. (4,669,473). Kensey discloses, in col. 5, lines 16-57, the method substantially as claimed, where the method includes the

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supplying of a first member (28) or sheath, a first resorbable segment (3) and a spreadable second resorbable segment (30). Kensey also discloses, in col. 5, lines 61-64 that a third segment can be slid down the first resorbable segment in order to produce tension on the first resorbable segment. However, Kensey does not disclose sliding a third resorbable segment along the first resorbable segment to apply for to the outer wall surface of the blood vessel to produce tension in the first resorbable segment. Richards et al. teach an occlusion system having a third resorbable segment (40b) slidable along a first resorbable segment (10b) for bearing upon tissue surrounding an opening (see fig. 9) and producing tension in the first resorbable segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Richards et al., to apply a third resorbable segment along the first resorbable segment to apply for to the outer wall surface of the blood vessel to produce tension in the first resorbable segment. Such a segment would not only produce tension in the first resorbable segment, it can be implanted in and eventually be absorbed in the patient's body and further seal the opening in the blood vessel wall—especially if the blood vessel opening is not in the proximity of skin that can act as support for the first resorbable segment.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mueller et al. (4,705,040) teach an assembly with a sheath, an occlusion element, a retaining thread, and a locking element.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

January 18, 2006